K112807

5. 510(k) Summary of Safety and Effectiveness

FEB 2 7 2012

Submission in accordance with the requirements of 21 CFR Part 807.87(h).

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Prepared	: February 17, 2012

Trade / Device Name	: X-RAY VVA
Common Name	: Radiological Image Processing Software
Regulatory Class	: II
Regulation Description	: Picture Archiving and Communications System
Regulation / Procode	: 21 CFR 892.2050 / LLZ

Predicate Devices

- The Medis medical imaging system bv: **QCA-CMS (K993763)**
- The Medis medical imaging system bv: **QLV-CMS (K993765)**
- The Medis medical imaging system bv: **QVA-CMS (K023970)**
- The Medis medical imaging system bv: **CMS-VIEW (K993761)**
- The Pie Medical Imaging bv: **CAAS (K052988)**

Device Description

X-RAY VVA (Vessel and Ventricular Analysis) is image post-processing software for the viewing and quantification of digital x-ray angiographic images of blood vessels and of the chambers of the heart. Semi-automatic contour detection forms the basis for the analyses. Its functionality is independent of the type of vendor acquisition equipment. The analysis results are available on screen, and can be exported in various electronic formats.

X-RAY VVA has been developed as a standalone application to run on a Windows based operating system. The import of images and the export of analysis results are via CD / DVD, a PACS or network environment.

X-RAY VVA has a modular structure that consists of its previously cleared predicate devices: QCA-CMS, QVA-CMS, QLV-CMS, and CMS-VIEW. X-RAY VVA comprises their respective functionalities for analyzing the blood vessels and the left ventricle. In addition, X-RAY VVA includes new functionality for the analysis of: the right ventricle, stent and sub-segments, coronary aneurysms, and bifurcations.

Intended Use

X-RAY VVA is software intended to be used for performing calculations in X-ray angiographic images of the chambers of the heart and of blood vessels. These calculations are based on contours that are either manually drawn by the clinician or trained medical technician who is operating the software, or automatically detected by the software and subsequently presented for review and manual editing.

X-RAY VVA is also intended to be used for performing caliper measurements. The results obtained are displayed on top of the images and provided in reports.

The analysis results obtained with X-RAY VVA are intended for use by cardiologists and radiologists:

- to support clinical decisions concerning the heart and vessels
- to support the evaluation of interventions or drug therapy applied for conditions of the heart and vessels.

Indications for Use

X-RAY VVA is indicated for use in clinical settings where validated and reproducible quantified results are needed to support the calculations in X-ray angiographic images of the chambers of the heart and of blood vessels, for use on individual patients with cardiovascular disease.

When the quantified results provided by X-RAY VVA are used in a clinical setting on X-ray images of an individual patient, they can be used to support the clinical decisions making for the diagnosis of the patient or the evaluation of the treatment applied. In this case, the results are explicitly not to be regarded as the sole, irrefutable basis for clinical diagnosis, and they are only intended for use by the responsible clinicians.

Substantial Equivalence Information

Medis X-RAY VVA has technological features and characteristics **similar to** QCA-CMS, QVA-CMS, QLV-CMS, CMS-VIEW, and the CAAS product from Pie Medical Imaging.

X-RAY VVA has the same intended uses as the predicate devices.

Conclusions

X-RAY VVA has the same intended uses as the predicate devices. X-RAY VVA also includes similar technical features and characteristics as the predicate devices.

Testing and validation have produced results consistent with design input requirements.

During the development, potential hazards were controlled by a risk management plan, including risk analysis, risk mitigation, verification and evaluation.

Medis concludes that X-RAY VVA is a safe and effective medical device, and is at least as safe and effective as its predicate devices. The use of X-RAY VVA does not change the intended use of X-ray image scanners, nor does the use of this software result in any new potential hazards.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

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Mr. Hans Reiber
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Re: K112807
Trade/Device Name: X-RAY VVA
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 17, 2012
Received: February 23, 2012

Dear Mr. Reiber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K112807

Device Name: X-RAY VVA

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Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

Division Sign-Off

Office of In Vitro Diagnostic Device

Evaluation and Safety

510(k) K112807